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23 August 1999

Dockets Management Branch, (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20850

RE: Docket No. 97P-0354

As Chairman of ASTM Committee F04 on Medical and Surgical Materials and Devices, and on behalf of the F04 Executive Subcommittee, I am responding to the Food and Drug Administration's (FDA) Notice of Panel Recommendation published in the Federal Register on 28 May 1999 (Vol. 64, No. 1 03/Friday, 28 May 1999).

We are pleased that several ASTM F04 standards have been included in the reclassification of the shoulder joint metal/polymer/metal nonconstrained or semi-constrained porous-coated uncemented prosthesis. However, **we** wish to note that the designations and titles of some of the standards cited have changed. Listed below is the most current information for those standards which have modified designations or titles.

Title/Designation Presented in <i>Federal Register</i>	Current Title and Designation
F 75-92 Standard Specification for Cast Cobalt-28 Chromium6 Molybdenum Alloy for Surgical Implant Applications	F 75-98 Standard Specification for Cobalt-28 Chromium-6 Molybdenum Casting Alloy and Cast Products for Surgical Implants (UNS R 30075)
F 136-96 Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial Alloy (R65401)) for Surgical Implant Applications	F 136-98 Standard Specification for Wrought Titanium6 Aluminum4 Vanadium ELI (Extra Low Interstitial) Alloy (UNS R56401) for Surgical Implant Applications
F 1147-95 Standard Test Method for Tension Testing of Porous Metal Coatings	F 1147-99 Standard Test Method for Tension Testing of Calcium Phosphate and Metallic Coatings
Title/Designation Presented in <i>Federal Register</i>	Current Title and Designation
F 1160-91 Standard Test Method for Constant Stress Amplitude Fatigue Testing of Porous Metal-Coated Metallic Materials	F 1160-98 Standard Test Method for Shear and Bending Fatigue Testing of Calcium Phosphate and Metallic Medical Coatings


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F 1377-92 Standard Specification for Cobalt-28 Chromium6 Molybdenum Powder for Coating of Orthopedic Implants	F 1377-98a Standard Specification for Cobalt-28 Chromium-6 Molybdenum Powder for Coating of Orthopedic Implants UNS-R30075
F 1378-97 Standard Specification for Shoulder Prostheses	F 1378-99 Standard Specification for Shoulder Prostheses

If you have any questions about these documents, please contact Teresa Cendrowska, F04 Manager, at 610-832-9718 or tcendrow@astm.org.

Sincerely,


 Jack Lemons, Ph.D.
 Chairman, **ASTM Committee F04**

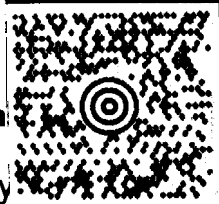
cc: F04 Executive Subcommittee
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